

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Oct 2026

Effects of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf mixture on type 2 diabetic patients

Protocol summary

Summary

This project aims to investigate the effect of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extract mixture on fasting blood glucose and glycosylated hemoglobin in patients with type 2 diabetes. Total 60 type 2 diabetic patients aged 40 to 60 years with fasting serum glucose levels of 150 to 180 mg/dL and glycosylated hemoglobin of 7.5 to 8.5 percent, referring to Diabetic Clinic in Baghiyatallah Hospital will be randomly and equally selected into herbal drug and placebo groups. Herbal drug is mixture of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extracts and placebo is prepared using toast powder. The patients in herbal group will be taken a Herbal drug capsule three times daily for 3 months and placebo group will be taken placebo capsule in the same manner. The patient antidiabetic drugs or other treatments will be continued and unchanged during the study. Before and at end of the study the blood biochemical tests, including fasting blood glucose and glycosylated hemoglobin are determined as primary outcomes and fasting blood triglycerides, cholesterol, low-density lipoprotein, high-density lipoprotein, aspartate aminotransferase, alanine aminotransferase, creatinine and blood urea nitrogen are determined as secondary outcomes. All data of herbal group are compared to placebo group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502011157N9**
Registration date: **2015-03-06, 1393/12/15**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-06, 1393/12/15

Registrant information

Name

Hasan Fallah Huseini

Name of organization / entity

Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4010

Email address

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Recruitment status

Recruitment complete

Funding source

Institute of Medicinal Plants

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf mixture on type 2 diabetic patients

Public title

To investigate the effect of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extracts mixture on blood sugar and glycosylated hemoglobin in type 2 diabetic patients: a double blind, randomized, placebo controlled trial.

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Type 2 diabetic patients; aged 40 to 60 years; fasting blood glucose levels from 150 to 180 mg/dL; blood glycosylated hemoglobin levels from 7.5 to 8.5 percent; under therapy of oral anti-hyperglycemic drugs maximum 10 mg glyburide and 1000 mg metformin daily. Exclusion criteria: Patients receiving insulin therapy; patients with cardiovascular, renal, hepatic, hematological, hypothyroidism, vertigo and seizure diseases; patients with a history of gallstones or gall bladder surgery; patients under estrogen, steroid, beta-blocker and thiazide therapy; pregnant women; women planning for pregnancy and breast-feeding women.

Age
 From **40 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 The study will not be conducted in the Ramazan month and Norooz days

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Avicenna Research Institute

Street address
 Shariati AVE, Yakhchal street, Avicenna Research Institute Central Building

City
 Tehran

Postal code

Approval date
 2015-02-20, 1393/12/01

Ethics committee reference number
 Under consideration

Health conditions studied

1

Description of health condition studied
 Diabetes

ICD-10 code
 E10, E14,

ICD-10 code description
 Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
 Fasting blood glucose

Timepoint
 At starting of the study and after 3 months

Method of measurement
 Blood glucose level will be determined in laboratory by commercially available kit

2

Description
 Glycosylated hemoglobin (HbA1c)

Timepoint
 At starting of the study and after 3 months

Method of measurement
 HbA1c percent will be determined in laboratory by commercially available kit

Secondary outcomes

1

Description
 Cholesterol

Timepoint
 At starting of the study and after 3 months

Method of measurement
 Blood cholesterol level will be determined in laboratory by commercially available kit

2

Description
 Triglyceride

Timepoint
 At starting of the study and after 3 months

Method of measurement
 Blood triglyceride level will be determined in laboratory by commercially available kit

3

Description
 High-density lipoprotein (HDL)

Timepoint
 At starting of the study and after 3 months

Method of measurement

Blood HDL level will be determined in laboratory by commercially available kit

4

Description

Aspartate aminotransferase (AST)

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood AST level will be determined in laboratory by commercially available kit

5

Description

Alanine aminotransferase (ALT)

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood ALT level will be determined in laboratory by commercially available kit

6

Description

Blood urea nitrogen (BUN)

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood BUN level will be determined in laboratory by commercially available kit

7

Description

Creatinine

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood creatinine level will be determined in laboratory by commercially available kit

8

Description

low-density lipoprotein (LDL)

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood LDL level will be determined in laboratory by commercially available kit

Intervention groups

1

Description

Herbal Drug: 600 mg 3 times a day after food

Category

Treatment - Drugs

2

Description

Placebo: 600 mg 3 times a day after food

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah Hospital

Full name of responsible person

Dr. Reza Mohtashami

Street address

Baghiatallah Medical College, Mollasadra Street, Vanak Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Institute of Medicinal Plants

Full name of responsible person

Reza Hajiaghaee

Street address

Research Complex of Jihad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55-kilometer of the Tehran-Qazvin Highway

City

Karaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Institute of Medicinal Plants

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Institute of Medicinal Plants

Full name of responsible person

Hasan Fallah Huseini

Position

Ph.D. in Pharmacology

Other areas of specialty/work**Street address**

Research Complex of Jihad Daneshgahi, Kavosh
Boulevard, Supa Boulevard, 55-kilometer of the
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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Fax**Email****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty